



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: André Lieber et al. **Examiner:** Not yet known
Serial No.: 09/980,564 **Group Art Unit:** 1633
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Title: RECOMBINANT ADENOVIRAL VECTORS EXPRESSING CHIMERIC
FIBER PROTEINS FOR CELL SPECIFIC INFECTION AND GENOME
INTEGRATION

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on April 24, 2002.

Renato Marco P. Domingo
By: Renato Marco P. Domingo

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b)(3))

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

- U.S. Patent No. 5,856,152 issued January 5, 1999 – **Exhibit 1**
- International Publication No. WO94/06920 published March 31, 1994 – **Exhibit 2**
- International Publication No. WO97/38723 published October 23, 1997 – **Exhibit 3**
- International Publication No. WO98/54346 published December 3, 1998 – **Exhibit 4**
- Alexander, Ian E. et al., "DNA-Damaging Agents Greatly Increase the Transduction of Nondividing Cells by Adeno-Associated Virus Vectors," *Journal of Virology*, 68:8282-7, 1994 – **Exhibit 5**
- Alexander, Ian E. et al., "Effects of Gamma Irradiation on the Transduction of Dividing and Nondividing Cells in Brain and Muscle of Rats by Adeno-Associated Virus Vectors," *Human Gene Therapy*, 7:841-50, 1996 – **Exhibit 6**

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- Antoniou, Michael et al., "Efficient 3'-end formation of human β -globin mRNA *in vivo* requires sequences with the last intron but occurs independently of the splicing reaction," *Nucleic Acids Research*, 26:721-9, 1998 – **Exhibit 7**
- Balagué, Cristina et al., "Adeno-Associated Virus Rep78 Protein and Terminal Repeats Enhance Integration of DNA Sequences into the Cellular Genome," *Journal of Virology*, 71:3299-306, 1997 – **Exhibit 8**
- Balagué, Cristina et al., "Sustained high-level expression of full-length human factor VIII and restoration of clotting activity in hemophilic mice using a minimal adenovirus vector," *Blood*, 95:820-8, 2000 – **Exhibit 9**
- Bhatia, Mickie et al., "A newly discovered class of human hematopoietic cells with SCID-repopulating activity," *Nature Medicine*, 4:1038-45, 1998 – **Exhibit 10**
- Becker, Pamela S. et al., "Adhesion receptor expression by hematopoietic cell lines and murine progenitors: Modulation by cytokines and cell cycle status," *Experimental Hematology*, 27:533-41, 1999 – **Exhibit 11**
- Bergelson, Jeffrey M. et al., "Isolation of a Common Receptor for Coxsackie B Viruses and Adenoviruses 2 and 5," *Science*, 275:1320-3, 1997 – **Exhibit 12**
- Berns, Kenneth I., "Parvoviridae: The Viruses and Their Replication," *Fields Virology*, 3rd Edition, B.N. Fields et al. (eds.), Lippincott-Raven Publishers, PA, 2:2173-97, 1996 – **Exhibit 13**
- Blau, C. Anthony et al., "Fetal Hemoglobin in Acute and Chronic States of Erythroid Expansion," *Blood*, 81:227-33, 1993 – **Exhibit 14**
- Boyer, Julie et al., "Adenovirus E4 34k and E4 11k Inhibit Double Strand Break Repair and Are Physically Associated with the Cellular DNA-Dependent Protein Kinase," *Virology*, 263:307-12, 1999 – **Exhibit 15**
- Bregni, M. et al., "Adenovirus vectors for gene transduction into mobilized blood CD34⁺ cells," *Gene Therapy*, 5:465-72, 1998 – **Exhibit 16**
- Burcin, Mark M. et al. "Adenovirus-mediated regulable target gene expression *in vivo*," *Proc Natl Acad Sci USA*, 96:355-60, 1999 – **Exhibit 17**

- Byk, Tamara et al., "Lipofectamine and Related Cationic Lipids Strongly Improve Adenoviral Infection Efficiency of Primitive Human Hematopoietic Cells," *Human Gene Therapy*, 9:2493-502, 1998 – **Exhibit 18**
- Cantwell, Mark J. et al., "Adenovirus Vector Infection of Chronic Lymphocytic Leukemia B Cells," *Blood*, 88:4676-83, 1996 – **Exhibit 19**
- Case, Scott S. et al., "Stable transduction of quiescent CD34⁺CD38⁻ human hematopoietic cells by HIV-1-based lentiviral vectors," *Proc Natl Acad Sci USA*, 96:2988-93, 1999 – **Exhibit 20**
- Cerami, Carla et al., "The Basolateral Domain of the Hepatocyte Plasma Membrane Bears Receptors for the Circumsporozoite Protein of *Plasmodium falciparum* Sporozoites," *Cell*, 70:1021-33, 1992 – **Exhibit 21**
- Challberg, Sharon S. and Gary Ketner, "Deletion Mutants of Adenovirus 2: Isolation and Initial Characterization of Virus Carrying Mutations Near the Right End of the Viral Genome," *Virology*, 114:196-209, 1981 – **Exhibit 22**
- Chartier, C. et al., "Efficient Generation of Recombinant Adenovirus Vectors by Homologous Recombination in *Escherichia coli*," *Journal of Virology*, 70:4805-10, 1996 – **Exhibit 23**
- Chatterjee, Shyama et al., "A Conserved Peptide Sequence of the *Plasmodium falciparum* Circumsporozoite Protein and Antipeptide Antibodies Inhibit *Plasmodium berghei* Sporozoite Invasion of Hep-G2 Cells and Protect Immunized Mice against *P. berghei* Sporozoite Challenge," *Infection and Immunity*, 63:4375-81, 1995 – **Exhibit 24**
- Chen, Hsiaoli et al., "Analysis of enhancer function of the HS-40 core sequence of the human α -globin cluster," *Nucleic Acids Research*, 25:2917-22, 1997 – **Exhibit 25**
- Chillon, Miguel et al., "Group D Adenoviruses Infect Primary Central Nervous System Cells More Efficiently than Those from Group C," *Journal of Virology*, 73:2537-40, 1999 – **Exhibit 26**
- Chroboczek, J. et al., "Adenovirus Fiber," *Current Topics in Microbiology and Immunology*, W. Doerfler and P. Böhm (eds.), Springer, 1:163-200, 1995 – **Exhibit 27**

- Chung, Jay H. et al., "Characterization of the chicken β -globin insulator," *Proc Natl Acad Sci USA*, 94:575-80, 1997 – **Exhibit 28**
- Crompton, Janet et al., "Expression of a foreign epitope on the surface of the adenovirus hexon," *The Journal of General Virology*, 75:133-9, 1994 – **Exhibit 29**
- Dao, Mo A. et al., "Engraftment and Retroviral Marking of CD34⁺ and CD34⁺CD38⁻ Human Hematopoietic Progenitors Assessed in Immune-Deficient Mice," *Blood*, 91:1243-55, 1998 – **Exhibit 30**
- Davison, A. J. et al., "The DNA Sequence of Adenovirus Type 40," *Journal of Molecular Biology*, 234:1308-16, 1993 – **Exhibit 31**
- Dayhoff, M. O. et al., "A Model of Evolutionary Change in Proteins," *Atlas of Protein Sequence and Structure*, Supplement 3, 5:345-52, 1978 – **Exhibit 32**
- Defer, Christine et al., "Human Adenovirus-Host Cell Interactions: Comparative Study with Members of Subgroups B and C," *Journal of Virology*, 64:3661-73, 1990 – **Exhibit 33**
- Doi, N. and H. Yanagawa, "Screening of conformationally constrained random polypeptide libraries displayed on a protein scaffold," *Cellular and Molecular Life Sciences*, 54:394-404, 1998 – **Exhibit 34**
- Dunaway, Marietta et al., "The Activity of the scs and scs' Insulator Elements Is Not Dependent on Chromosomal Context", *Molecular and Cellular Biology*, 17:182-9, 1997 – **Exhibit 35**
- Ellerby, H. Michael et al., "Anti-cancer activity of targeted pro-apoptotic peptides," *Nature Medicine*, 5:1032-8, 1999 – **Exhibit 36**
- Ellis, James et al., "A dominant chromatin-opening activity in 5' hypersensitive site 3 of the human β -globin locus control region," *The EMBO Journal*, 15:562-8, 1996 – **Exhibit 37**
- Ellis, James et al., "Evaluation of β -globin gene therapy constructs in single copy transgenic mice," *Nucleic Acid Research*, 25:1296-302, 1997 – **Exhibit 38**
- Emery, David W. et al., "Analysis of γ -Globin Expression Cassettes in Retrovirus Vectors," *Human Gene Therapy*, 10:877-888, 1999 – **Exhibit 39**

- Everitt, E. and E. Rodríguez, "Adenovirus cellular receptor site recirculation of HeLa cells upon receptor-mediated endocytosis is not low pH-dependent," *Archives of Virology*, 144:787-95, 1999 – **Exhibit 40**
- Felsenfeld, Gary et al., "Chromatin structure and gene expression," *Proc Natl Acad Sci USA*, 93:9384-8, 1996 – **Exhibit 41**
- Fiering, Steven N. et al., "Improved FACS-Gal: Flow Cytometric Analysis and Sorting of Viable Eukaryotic Cells Expressing Reporter Gene Constructs," *Cytometry*, 12:291-301, 1991 – **Exhibit 42**
- Floch, Virginie et al., "Cationic Phosphonolipids as non Viral Vectors for DNA Transfection in Hematopoietic Cell Lines and CD34⁺ Cells," *Blood Cells, Molecules & Diseases*, 23:69-87, 1997 – **Exhibit 43**
- Flomenberg, Phyllis R. et al., "Molecular Epidemiology of Adenovirus Type 35 Infections in Immunocompromised Hosts," *The Journal of Infectious Diseases*, 155:1127-34, 1987 – **Exhibit 44**
- Flomenberg, Phyllis et al., "Increasing Incidence of Adenovirus Disease in Bone Marrow Transplant Recipients," *The Journal of Infectious Diseases*, 169:775-81, 1994 – **Exhibit 45**
- Forrester, William C. et al., "A developmentally stable chromatin structure in the human β -globin gene cluster," *Proc Natl Acad Sci USA*, 83:1359-63, 1986 – **Exhibit 46**
- Fraser, Peter and Frank Grosveld, "Locus control regions, chromatin activation and transcription," *Current Opinion in Cell Biology*, 10:361-5, 1998 – **Exhibit 47**
- Gall, Jason et al., "Adenovirus Type 5 and 7 Capsid Chimera: Fiber Replacement Alters Receptor Tropism without Affecting Primary Immune Neutralization Epitopes," *Journal of Virology*, 70:2116-23, 1996 – **Exhibit 48**
- Gonzales, R. et al., "Increased gene transfer in acute myeloid leukemic cells by an adenovirus vector containing a modified fiber protein," *Gene Therapy*, 6:314-20, 1999 – **Exhibit 49**
- Goodell, Margaret A. et al., "Dye efflux studies suggest that hematopoietic stem cells expressing low or undetectable levels of CD34 antigen exist in multiple species," *Nature Medicine*, 3:1337-45, 1997 – **Exhibit 50**

- Grosveld, Frank et al., "The Dynamics of Globin Gene Expression and Gene Therapy Vectors," *Seminars in Hematology*, 35:105-111, 1998 – **Exhibit 51**
- Gruber, William C. et al., "Fiber Gene and Genomic Origin of Human Adenovirus Type 4," *Virology*, 196:603-611, 1993 – **Exhibit 52**
- Heffelfinger, Sue C. et al., "SK HEP-1: A Human Cell Line of Endothelial Origin," *In Vitro Cellular and Developmental Biology*, 28A:136-42, 1992 – **Exhibit 53**
- Hitt, Mary M. et al., "Human Adenovirus Vectors for Gene Transfer into Mammalian Cells," *Advances in Pharmacology*, J. Thomas August (ed.), Academic Press, 40:137-206, 1997 – **Exhibit 54**
- Horwitz, Marshall S., "Adenoviruses," *Fields Virology*, 3rd Edition, B.N. Fields et al. (eds.), Lippincott-Raven Publishers, PA, 2:2149-71, 1996 – **Exhibit 55**
- Hsu, Kuo-Hom Lee et al., "A Monoclonal Antibody Specific for the Cellular Receptor for the Group B Coxsackieviruses," *Journal of Virology*, 62:1647-52, 1988 – **Exhibit 56**
- Huang, Shuang et al., "Upregulation of Integrins $\alpha v \beta 3$ and $\alpha v \beta 5$ on Human Monocytes and T Lymphocytes Facilitates Adenovirus-Mediated Gene Delivery," *Journal of Virology*, 69:2257-63, 1995 – **Exhibit 57**
- Huang, Shuang et al., "Adenovirus Interaction with Distinct Integrins Mediates Separate Events in Cell Entry and Gene Delivery to Hematopoietic Cells," *Journal of Virology*, 70:4502-8, 1996 – **Exhibit 58**
- Ikuta, Koichi and Irving L. Weissman, "Evidence that hematopoietic stem cells express mouse *c-kit* but do not depend on steel factor for their generation," *Proc Natl Acad Sci USA*, 89:1502-6, 1992 – **Exhibit 59**
- Kay, Mark A. et al., "Therapeutic Serum Concentrations of Human Alpha-1-Antitrypsin After Adenoviral-Mediated Gene Transfer Into Mouse Hepatocytes," *Hepatology*, 21:815-9, 1995 – **Exhibit 60**
- Kirby, Ian et al., "Identification of Contact Residues and Definition of the CAR-Binding Site of Adenovirus Type 5 Fiber Protein," *Journal of Virology*, 74:2804-3, 2000 – **Exhibit 61**

- Klehr, Dagmar et al., "Scaffold-Attached Regions from the Human Interferon β Domain Can Be Used To Enhance the Stable Expression of Genes under the Control of Various Promoters," *Biochemistry*, 30:1264-70, 1991 – **Exhibit 62**
- Koivunen, Erkki et al., "Phage Libraries Displaying Cyclic Peptides with Different Ring Sizes: Ligand Specificities of the RGD-Directed Integrins," *Bio/Technology*, 13:265-70, 1995 – **Exhibit 63**
- Koivunen, Erkki et al., "Tumor targeting with a selective gelatinase inhibitor," *Nature Biotechnology*, 17:768-74, 1999 – **Exhibit 64**
- Krasnykh, Victor N. et al., "Generation of Recombinant Adenovirus Vectors with Modified Fibers for Altering Viral Tropism," *Journal of Virology*, 70:6839-46, 1996 – **Exhibit 65**
- Krasnykh, Victor et al., "Characterization of an Adenovirus Vector Containing a Heterologous Peptide Epitope in the HI Loop of the Fiber Knob," *Journal of Virology*, 72:1844-52, 1998 – **Exhibit 66**
- Krause, Diane S. et al., "Regulation of CD34 expression in differentiating M1 cells," *Experimental Hematology*, 25:1051-61, 1997 – **Exhibit 67**
- Kwoh, T. Jesse et al., "Introduction and expression of the bacterial *PaeR7* methylase gene in mammalian cells," *Proc Natl Acad Sci USA*, 83:7713-7, 1986 – **Exhibit 68**
- Langer, Stephen J. and Jerome Schaack, "293 Cell Lines That Inducibly Express High Levels of Adenovirus Type 5 Precursor Terminal Protein," *Virology*, 221:172-9, 1996 – **Exhibit 69**
- Legrand, V. et al., "Fiberless Recombinant Adenoviruses: Virus Maturation and Infectivity in the Absence of Fiber," *Journal of Virology*, 73:907-19, 1999 – **Exhibit 70**
- Li, Qiliang et al., "Development of Viral Vectors for Gene Therapy of β -Chain Hemoglobinopathies: Optimization of a γ -Globin Gene Expression Cassette," *Blood*, 93:2208-16, 1999 – **Exhibit 71**
- Lieber, André et al., "Adenovirus-Mediated Transfer of the Amphotropic Retrovirus Receptor cDNA Increases Retroviral Transduction in Cultured Cells," *Human Gene Therapy*, 6:5-11, 1995 – **Exhibit 72**

- Lieber, André and Mark A. Kay, "Adenovirus-Mediated Expression of Ribozymes in Mice," *Journal of Virology*, 70:3153-8, 1996 – **Exhibit 73**
- Lieber, André et al., "Elimination of Hepatitis C Virus RNA in Infected Human Hepatocytes by Adenovirus-Mediated Expression of Ribozymes," *Journal of Virology*, 70:8782-91, 1996 – **Exhibit 74**
- Lieber, André et al., "Recombinant Adenoviruses with Large Deletions Generated by Cre-Mediated Excision Exhibit Different Biological Properties Compared with First-Generation Vectors In Vitro and In Vivo," *Journal of Virology*, 70:8944-60, 1996 – **Exhibit 75**
- Lieber, André et al., "The Role of Kupffer Cell Activation and Viral Gene Expression in Early Liver Toxicity after Infusion of Recombinant Adenovirus Vectors," *Journal of Virology*, 71:8798-807, 1997 – **Exhibit 76**
- Lieber, André et al., "Inhibition of NF- κ B Activation in Combination with Bcl-2 Expression Allows for Persistence of First-Generation Adenovirus Vectors in the Mouse Liver," *Journal of Virology*, 72:9267-77, 1998 – **Exhibit 77**
- Lieber, André et al., "Integrating Adenovirus – Adeno-Associated Virus Hybrid Vectors Devoid of All Viral Genes," *Journal of Virology*, 73:9314-24, 1999 – **Exhibit 78**
- Lietner, Agnes et al., "Lack of DNA synthesis among CD34⁺ cells in cord blood and in cytokine-mobilized blood," *British Journal of Haematology*, 92:255-62, 1996 – **Exhibit 79**
- Lyu, Yi Lisa et al., "Inversion/Dimerization of Plasmids Mediated by Inverted Repeats," *Journal of Molecular Biology*, 285:1485-501, 1999 – **Exhibit 80**
- Maizel, Jacob V., Jr. et al., "The Polypeptides of Adenovirus – Evidence for Multiple Protein Components in the Virion and a Comparison of Types 2, 7A, and 12," *Virology*, 36:115-25, 1968 – **Exhibit 81**
- Malik, Punam et al., "Recombinant Adeno-Associated Virus Mediates a High Level of Gene Transfer but Less Efficient Integration in the K562 Human Hematopoietic Cell Line," *Journal of Virology*, 71:1776-83, 1997 – **Exhibit 82**
- Martin, David I. K. et al., "Regulation of β -globin gene expression: straightening out the locus," *Current Opinion in Genetics & Development*, 6:488-95, 1996 – **Exhibit 83**

- Mathias, P. et al., "Multiple Adenovirus Serotypes Use αv -Integrins for Infection," *Journal of Virology*, 68:6811-4, 1994 – **Exhibit 84**
- Matsunaga, Takuya et al., "Thrombopoietin Promotes the Survival of Murine Hematopoietic Long-Term Reconstituting Cells: Comparison With the Effects of FLT3/FLK-2 Ligand and Interleukin-6," *Blood*, 92:452-61, 1998 – **Exhibit 85**
- May, Gillian and Tariq Enver, "Targeting gene expression to haemopoietic stem cells: a chromatin-dependent upstream element mediates cell type-specific expression of the stem cell antigen CD34," *The EMBO Journal*, 14:564-74, 1995 – **Exhibit 86**
- McGuckin, Colin P. et al., "A novel approach to investigating the erythroid lineage, using both receptor analysis and haemoglobin detection," *British Journal of Haematology*, 95:457-60, 1996 – **Exhibit 87**
- Michael, S. I. et al., "Addition of a short peptide ligand to the adenovirus fiber protein," *Gene Therapy*, 2:660-8, 1995 – **Exhibit 88**
- Mitani, Kohnoske et al., "Transduction of Human Bone Marrow by Adenoviral Vector," *Human Gene Therapy*, 5:941-8, 1994 – **Exhibit 89**
- Mittereder, Nanette et al., "Evaluation of the Concentration and Bioactivity of Adenovirus Vectors for Gene Therapy," *Journal of Virology*, 70:7498-509, 1996 – **Exhibit 90**
- Miyazawa, Naoki et al., "Fiber Swap between Adenovirus Subgroups B and C Alters Intracellular Trafficking of Adenovirus Gene Transfer Vectors," *Journal of Virology*, 73:6056-65, 1999 – **Exhibit 91**
- Mizuguchi, Hiroyuki and Mark A. Kay, "Efficient Construction of a Recombinant Adenovirus Vector by an Improved *In Vitro* Ligation Method," *Human Gene Therapy*, 9:2577-83, 1998 – **Exhibit 92**
- Mohler, William A. and Helen M. Blau, "Gene expression and cell fusion analyzed by *lacZ* complementation in mammalian cells," *Proc Natl Acad Sci USA*, 93:12423-7, 1996 – **Exhibit 93**
- Moore, Kateri A. et al., "In Vitro Maintenance of Highly Purified, Transplantable Hematopoietic Stem Cells," *Blood*, 89:4337-47, 1997 – **Exhibit 94**

- Neering, Sarah J. et al., "Transduction of Primitive Human Hematopoietic Cells With Recombinant Adenovirus Vectors," *Blood*, 88:1147-55, 1996 – **Exhibit 95**
- Nelson, James E. and Mark A. Kay, "Persistence of Recombinant Adenovirus In Vivo Is Not Dependent on Vector DNA Replication," *Journal of Virology*, 71:8902-7, 1997 – **Exhibit 96**
- Neu, Stefan et al., "Isolation and Phenotypic Characterization of CD117-Positive Cells," *Leukemia Research*, 20:963-71, 1996 – **Exhibit 97**
- Nicolás, Andrea L. et al., "Creation and Repair of Specific DNA Double-Strand Breaks *in Vivo* Following Infection with Adenovirus Vectors Expressing *Saccharomyces cerevisiae* HO Endonuclease," *Virology*, 266:211-24, 2000 – **Exhibit 98**
- Osawa, Masatake et al., "Long-Term Lymphohematopoietic Reconstitution by a Single CD34-Low/Negative Hematopoietic Stem Cell," *Science*, 273:242-5, 1996 – **Exhibit 99**
- Papayannopoulou, Thalia et al., "Insights into the cellular mechanisms of erythropoietin-thrombopoietin synergy," *Experimental Hematology*, 24:660-9, 1996 – **Exhibit 100**
- Papayannopoulou, T. and C. Craddock, "Homing and Trafficking of Hemopoietic Progenitor Cells," *Acta Haematologica*, 97:97-104, 1997 – **Exhibit 101**
- Pasqualini, Renata and Erkki Ruoslahti, "Organ targeting *in vivo* using phage display peptide libraries," *Nature*, 380:364-6, 1996 – **Exhibit 102**
- Pring-Åkerblom, Patricia et al., "Molecular Characterization of Hemagglutination Domains on the Fibers of Subgenus D Adenoviruses," *Journal of Virology*, 72:2297-304, 1998 – **Exhibit 103**
- Qing, Keyun et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Correlation of Tyrosine Phosphorylation of the Cellular Single-Stranded D Sequence-Binding Protein with Transgene Expression in Human Cells In Vitro and Murine Tissues In Vivo," *Journal of Virology*, 72:1593-9, 1998 – **Exhibit 104**
- Recchia, Alessandra et al., "Site-specific integration mediated by a hybrid adenovirus/adenovirus-associated virus vector," *Proc Natl Acad Sci USA*, 96:2615-20, 1999 – **Exhibit 105**

- Roberts, Andrew W. and Donald Metcalf, "Noncycling State of Peripheral Blood Progenitor Cells Mobilized by Granulocyte Colony-Stimulating Factor and Other Cytokines," *Blood*, 86:1600-5, 1995 – **Exhibit 106**
- Roelvink, Peter W. et al., "Comparative Analysis of Adenovirus Fiber-Cell Interaction: Adenovirus Type 2 (Ad2) and Ad9 Utilize the Same Cellular Fiber Receptor but Use Different Binding Strategies for Attachment," *Journal of Virology*, 70:7614-21, 1996 – **Exhibit 107**
- Roelvink, Peter W. et al., "The Coxsackievirus-Adenovirus Receptor Protein Can Function as a Cellular Attachment Protein for Adenovirus Serotypes from Subgroups A, C, D, E, and F," *Journal of Virology*, 72:7909-15, 1998 – **Exhibit 108**
- Rouet, Philippe et al., "Expression of a site-specific endonuclease stimulates homologous recombination in mammalian cells," *Proc Natl Acad Sci USA*, 91:6064-8, 1994 – **Exhibit 109**
- Roy, Vivek and Catherine M. Verfaillie, "Expression and function of cell adhesion molecules on fetal liver, cord blood and bone marrow hematopoietic progenitors: Implications for anatomical localization and developmental stage specific regulation of hematopoiesis," *Experimental Hematology*, 27:302-12, 1999 – **Exhibit 110**
- Russell, David W. et al., "Adeno-associated virus vectors preferentially transduce cells in S phase," *Proc Natl Acad Sci USA*, 91:8915-9, 1994 – **Exhibit 111**
- Russell, David W. et al., "DNA synthesis and topoisomerase inhibitors increase transduction by adeno-associated virus vectors," *Proc Natl Acad Sci USA*, 92:5719-23, 1995 – **Exhibit 112**
- Rutledge, Elizabeth A. and David W. Russell, "Adeno-Associated Virus Vector Integration Junctions," *Journal of Virology*, 71:8429-36, 1997 – **Exhibit 113**
- Samulski, Richard Jude et al., "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression," *Journal of Virology*, 63:3822-8, 1989 – **Exhibit 114**

- Sánchez, Mariá-José et al., "Characterization of the First Definitive Hematopoietic Stem Cells in the AGM and Liver of the Mouse Embryo," *Immunity*, 5:513-25, 1996 – **Exhibit 115**
- Schiedner, Gudrun et al., "Genomic DNA transfer with a high-capacity adenovirus vector results in improved *in vivo* gene expression and decreased toxicity," *Nature Genetics*, 18:180-3, 1998 – **Exhibit 116**
- Shakibaei, Mehdi and Ute Frevert, "Dual Interaction of the Malaria Circumsporozoite Protein with the Low Density Lipoprotein Receptor-related Protein (LRP) and Heparan Sulfate Proteoglycans," *The Journal of Experimental Medicine*, 184:1699-711, 1996 – **Exhibit 117**
- Shenk, Thomas, "Adenoviridae: The Viruses and Their Replication," *Fields Virology*, 3rd Edition, B.N. Fields et al. (eds.), Lippincott-Raven Publishers, PA, 2:2111-48, 1996 – **Exhibit 118**
- Shields, Anthony F. et al., "Adenovirus Infections in Patients Undergoing Bone-Marrow Transplantation," *The New England Journal of Medicine*, 312:529-33, 1985 – **Exhibit 119**
- Shtrichman, Ronit and Tamar Kleinberger, "Adenovirus Type 5 E4 Open Reading Frame 4 Protein Induces Apoptosis in Transformed Cells," *Journal of Virology*, 72:2975-82, 1998 – **Exhibit 120**
- Simmons, Paul J. et al., "c-kit is expressed by primitive human hematopoietic cells that give rise to colony-forming cells in stroma-dependent or cytokine-supplemented culture," *Experimental Hematology*, 22:157-65, 1994 – **Exhibit 121**
- Steinwaerder, Dirk S. et al., "Generation of Adenovirus Vectors Devoid of All Viral Genes by Recombination between Inverted Repeats," *Journal of Virology*, 73:9303-13, 1999 – **Exhibit 122**
- Stevenson, Susan C. et al., "Human Adenovirus Serotypes 3 and 5 Bind to Two Different Cellular Receptors via the Fiber Head Domain," *Journal of Virology*, 69:2850-7, 1995 – **Exhibit 123**
- Stevenson, Susan C. et al., "Selective Targeting of Human Cells by a Chimeric Adenovirus Vector Containing a Modified Fiber Protein," *Journal of Virology*, 71:4782-90, 1997 – **Exhibit 124**

- Tiemessen, Caroline T. and Alistair H. Kidd, "The subgroup F adenoviruses," *The Journal of General Virology*, 76:481-97, 1995 – **Exhibit 125**
- Tollefson, Ann E. et al., "The Adenovirus Death Protein (E3-11.6K) Is Required at Very Late Stages of Infection for Efficient Cell Lysis and Release of Adenovirus from Infected Cells," *Journal of Virology*, 70:2296-306, 1996 – **Exhibit 126**
- Tomko, Richard P. et al., "HCAR and MCAR: The human and mouse cellular receptors for subgroup C adenoviruses and group B coxsackieviruses," *Proc Natl Acad Sci USA*, 94:3352-6, 1997 – **Exhibit 127**
- Van der Vliet, P. C., "Adenovirus DNA Replication," *Current Topics in Microbiology and Immunology*, W. Doerfler and P. Böhm (eds.), Springer, 2:1-30, 1995 – **Exhibit 128**
- Watanabe, Tsutomu et al., "Gene Transfer Into Human Bone Marrow Hematopoietic Cells Mediated by Adenovirus Vectors," *Blood*, 87:5032-9, 1996 – **Exhibit 129**
- Wickham, Thomas J. et al., "Integrins $\alpha_v\beta_3$ and $\alpha_v\beta_5$ Promote Adenovirus Internalization but Not Virus Attachment," *Cell*, 73:309-19, 1993 – **Exhibit 130**
- Wickham, T. J. et al., "Targeting of adenovirus penton base to new receptors through replacement of its RGD motif with other receptor-specific peptide motifs," *Gene Therapy*, 2:750-6, 1995 – **Exhibit 131**
- Wickham, Thomas J. et al., "Targeted Adenovirus Gene Transfer to Endothelial and Smooth Muscle Cells by Using Bispecific Antibodies," *Journal of Virology*, 70:6831-8, 1996 – **Exhibit 132**
- Wickham, Thomas J. et al., "Adenovirus targeted to heparan-containing receptors increases its gene delivery efficiency to multiple cell types," *Nature Biotechnology*, 14:1570-3, 1996 – **Exhibit 133**
- Xiao, Xiao et al., "A Novel 165-Base-Pair Terminal Repeat Sequence Is the Sole *cis* Requirement for the Adeno-Associated Virus Life Cycle," *Journal of Virology*, 71:941-8, 1997 – **Exhibit 134**
- Yamaguchia, Yuji et al., "Functional characterization of the promoter for the gene encoding murine CD34," *Biochimica et Biophysica Acta*, 1350:141-6, 1997 – **Exhibit 135**

- Yang, C. C. et al., "Cellular Recombination Pathways and Viral Terminal Repeat Hairpin Structures Are Sufficient for Adeno-Associated Virus Integration In Vivo and In Vitro," *Journal of Virology*, 71:9231-47, 1997 – **Exhibit 136**
- Yang, Yiping et al., "Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy," *Proc Natl Acad Sci USA*, 91:4407-11, 1994 – **Exhibit 137**
- Zanjani, Esmail D. et al., "Human bone marrow CD34⁺ cells engraft in vivo and undergo multilineage expression that includes giving rise to CD34⁺ cells," *Experimental Hematology*, 26:353-60, 1998 – **Exhibit 138**

This statement should be considered because it is submitted before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). In accordance with 37 C.F.R. §1.98(a)(2), copies of each document or other information listed on the enclosed Form 1449 are provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that the references have been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. § 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

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Serial No. 09/980,564
Filed: November 30, 2001
Page 15

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 50-0306.

Respectfully submitted,

A handwritten signature in cursive script that reads "Sarah B. Adriano". The signature is written in dark ink and is positioned above a horizontal line.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: André Lieber, et al.
Serial No.: 09/980,564
Filed: November 30, 2001
Docket: 30429.2USWO
Title: RECOMBINANT ADENOVIRAL VECTORS EXPRESSING CHIMERIC FIBER PROTEINS
FOR CELL SPECIFIC INFECTION AND GENOME INTEGRATION

TECH CENTER 1600/2900

APR 30 2002

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CERTIFICATE UNDER 37 CFR 1.8

I hereby certify that this paper or fee is being deposited with the United States Postal as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on April 24, 2002.

By: Renato Marco P. Dominguez
Name: Renato Marco P. Dominguez

35 N. Arroyo Parkway, Suite 60
Pasadena, California 91103
April 24, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.8
- ☒ Information Disclosure Statement (37 C.F.R. §1.97(b)(3)) (15 pages)
- ☒ Form 1449 (Information Disclosure Statement) (9 sheets)
- ☒ Exhibits 1-138 (138 References)
- ☒ Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

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Reg. No.: 34,470
Customer No. 26,941

FORM 1449*

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(Use several sheets if necessary)

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Applicant

André Lieber et al.

Filing Date

November 30, 2001

Group Art Unit

1633

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,856,152 (Exhibit 1)	01/05/99	Wilson et al.			10/28/94

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO94/06920 (Exhibit 2)	03/31/94	PCT				X
	WO97/38723 (Exhibit 3)	10/23/97	PCT				X
	WO98/54346 (Exhibit 4)	12/03/98	PCT				X

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Alexander, Ian E. et al., "DNA-Damaging Agents Greatly Increase the Transduction of Nondividing Cells by Adeno-Associated Virus Vectors," <i>Journal of Virology</i> , 68:8282-7, 1994 (Exhibit 5)
		Alexander, Ian E. et al., "Effects of Gamma Irradiation on the Transduction of Dividing and Nondividing Cells in Brain and Muscle of Rats by Adeno-Associated Virus Vectors," <i>Human Gene Therapy</i> , 7:841-50, 1996 (Exhibit 6)
TECH CENTER APR 30 2002 RECEIVED 1600/2900		Antoniou, Michael et al., "Efficient 3'-end formation of human β -globin mRNA <i>in vivo</i> requires sequences with the last intron but occurs independently of the splicing reaction," <i>Nucleic Acids Research</i> , 26:721-9, 1998 (Exhibit 7)
		Balagué, Cristina et al., "Adeno-Associated Virus Rep78 Protein and Terminal Repeats Enhance Integration of DNA Sequences into the Cellular Genome," <i>Journal of Virology</i> , 71:3299-306, 1997 (Exhibit 8)
		Balagué, Cristina et al., "Sustained high-level expression of full-length human factor VIII and restoration of clotting activity in hemophilic mice using a minimal adenovirus vector," <i>Blood</i> , 95:820-8, 2000 (Exhibit 9)
		Bhatia, Mickie et al., "A newly discovered class of human hematopoietic cells with SCID-repopulating activity," <i>Nature Medicine</i> , 4:1038-45, 1998 (Exhibit 10)
		Becker, Pamela S. et al., "Adhesion receptor expression by hematopoietic cell lines and murine progenitors: Modulation by cytokines and cell cycle status," <i>Experimental Hematology</i> , 27:533-41, 1999 (Exhibit 11)
		Bergelson, Jeffrey M. et al., "Isolation of a Common Receptor for Coxsackie B Viruses and Adenoviruses 2 and 5," <i>Science</i> , 275:1320-3, 1997 (Exhibit 12)

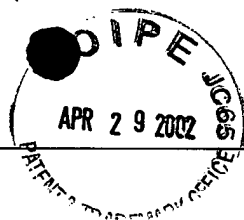
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	30429.2USWO	09/980,564
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	André Lieber et al.	
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	November 30, 2001	1633

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Berns, Kenneth I., "Parvoviridae: The Viruses and Their Replication," <i>Fields Virology</i> , 3 rd Edition, B.N. Fields et al. (eds.), Lippincott-Raven Publishers, PA, 2:2173-97, 1996 (Exhibit 13)
		Blau, C. Anthony et al., "Fetal Hemoglobin in Acute and Chronic States of Erythroid Expansion," <i>Blood</i> , 81:227-33, 1993 (Exhibit 14)
		Boyer, Julie et al., "Adenovirus E4 34k and E4 11k Inhibit Double Strand Break Repair and Are Physically Associated with the Cellular DNA-Dependent Protein Kinase," <i>Virology</i> , 263:307-12, 1999 (Exhibit 15)
		Bregni, M. et al., "Adenovirus vectors for gene transduction into mobilized blood CD34 ⁺ cells," <i>Gene Therapy</i> , 5:465-72, 1998 (Exhibit 16)
		Burcin, Mark M. et al. "Adenovirus-mediated regulable target gene expression <i>in vivo</i> ," <i>Proc Natl Acad Sci USA</i> , 96:355-60, 1999 (Exhibit 17)
		Byk, Tamara et al., "Lipofectamine and Related Cationic Lipids Strongly Improve Adenoviral Infection Efficiency of Primitive Human Hematopoietic Cells," <i>Human Gene Therapy</i> , 9:2493-502, 1998 (Exhibit 18)
		Cantwell, Mark J. et al., "Adenovirus Vector Infection of Chronic Lymphocytic Leukemia B Cells," <i>Blood</i> , 88:4676-83, 1996 (Exhibit 19)
		Case, Scott S. et al., "Stable transduction of quiescent CD34 ⁺ CD38 ⁻ human hematopoietic cells by HIV-1-based lentiviral vectors," <i>Proc Natl Acad Sci USA</i> , 96:2988-93, 1999 (Exhibit 20)
		Cerami, Carla et al., "The Basolateral Domain of the Hepatocyte Plasma Membrane Bears Receptors for the Circumsporozoite Protein of <i>Plasmodium falciparum</i> Sporozoites," <i>Cell</i> , 70:1021-33, 1992 (Exhibit 21)
		Challberg, Sharon S. and Gary Ketner, "Deletion Mutants of Adenovirus 2: Isolation and Initial Characterization of Virus Carrying Mutations Near the Right End of the Viral Genome," <i>Virology</i> , 114:196-209, 1981 (Exhibit 22)
		Chartier, C. et al., "Efficient Generation of Recombinant Adenovirus Vectors by Homologous Recombination in <i>Escherichia coli</i> ," <i>Journal of Virology</i> , 70:4805-10, 1996 (Exhibit 23)
		Chatterjee, Shyama et al., "A Conserved Peptide Sequence of the <i>Plasmodium falciparum</i> Circumsporozoite Protein and Antipeptide Antibodies Inhibit <i>Plasmodium berghei</i> Sporozoite Invasion of Hep-G2 Cells and Protect Immunized Mice against <i>P. berghei</i> Sporozoite Challenge," <i>Infection and Immunity</i> , 63:4375-81, 1995 (Exhibit 24)
		Chen, Hsiao-li et al., "Analysis of enhancer function of the HS-40 core sequence of the human α -globin cluster," <i>Nucleic Acids Research</i> , 25:2917-22, 1997 (Exhibit 25)
		Chillon, Miguel et al., "Group D Adenoviruses Infect Primary Central Nervous System Cells More Efficiently than Those from Group C," <i>Journal of Virology</i> , 73:2537-40, 1999 (Exhibit 26)
		Chroboczek, J. et al., "Adenovirus Fiber," <i>Current Topics in Microbiology and Immunology</i> , W. Doerfler and P. Böhm (eds.), Springer, 1:163-200, 1995 (Exhibit 27)
		Chung, Jay H. et al., "Characterization of the chicken β -globin insulator," <i>Proc Natl Acad Sci USA</i> , 94:575-80, 1997 (Exhibit 28)
		Crompton, Janet et al., "Expression of a foreign epitope on the surface of the adenovirus hexon," <i>The Journal of General Virology</i> , 75:133-9, 1994 (Exhibit 29)

EXAMINER	DATE CONSIDERED
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		Dao, Mo A. et al., "Engraftment and Retroviral Marking of CD34 ⁺ and CD34 ⁺ CD38 ⁻ Human Hematopoietic Progenitors Assessed in Immune-Deficient Mice," <i>Blood</i> , 91:1243-55, 1998 (Exhibit 30)
		Davison, A. J. et al., "The DNA Sequence of Adenovirus Type 40," <i>Journal of Molecular Biology</i> , 234:1308-16, 1993 (Exhibit 31)
		Dayhoff, M. O. et al., "A Model of Evolutionary Change in Proteins," <i>Atlas of Protein Sequence and Structure</i> , Supplement 3, 5:345-52, 1978 (Exhibit 32)
		Defer, Christine et al., "Human Adenovirus-Host Cell Interactions: Comparative Study with Members of Subgroups B and C," <i>Journal of Virology</i> , 64:3661-73, 1990 (Exhibit 33)
		Doi, N. and H. Yanagawa, "Screening of conformationally constrained random polypeptide libraries displayed on a protein scaffold," <i>Cellular and Molecular Life Sciences</i> , 54:394-404, 1998 (Exhibit 34)
		Dunaway, Marietta et al., "The Activity of the scs and scs' Insulator Elements Is Not Dependent on Chromosomal Context", <i>Molecular and Cellular Biology</i> , 17:182-9, 1997 (Exhibit 35)
		Ellerby, H. Michael et al., "Anti-cancer activity of targeted pro-apoptotic peptides," <i>Nature Medicine</i> , 5:1032-8, 1999 (Exhibit 36)
		Ellis, James et al., "A dominant chromatin-opening activity in 5' hypersensitive site 3 of the human β -globin locus control region," <i>The EMBO Journal</i> , 15:562-8, 1996 (Exhibit 37)
		Ellis, James et al., "Evaluation of β -globin gene therapy constructs in single copy transgenic mice," <i>Nucleic Acid Research</i> , 25:1296-302, 1997 (Exhibit 38)
		Emery, David W. et al., "Analysis of γ -Globin Expression Cassettes in Retrovirus Vectors," <i>Human Gene Therapy</i> , 10:877-888, 1999 (Exhibit 39)
		Everitt, E. and E. Rodríguez, "Adenovirus cellular receptor site recirculation of HeLa cells upon receptor-mediated endocytosis is not low pH-dependent," <i>Archives of Virology</i> , 144:787-95, 1999 (Exhibit 40)
		Felsenfeld, Gary et al., "Chromatin structure and gene expression," <i>Proc Natl Acad Sci USA</i> , 93:9384-8, 1996 (Exhibit 41)
		Fiering, Steven N. et al., "Improved FACS-Gal: Flow Cytometric Analysis and Sorting of Viable Eukaryotic Cells Expressing Reporter Gene Constructs," <i>Cytometry</i> , 12:291-301, 1991 (Exhibit 42)
		Floch, Virginie et al., "Cationic Phosphonolipids as non Viral Vectors for DNA Transfection in Hematopoietic Cell Lines and CD34 ⁺ Cells," <i>Blood Cells, Molecules & Diseases</i> , 23:69-87, 1997 (Exhibit 43)
		Flomenberg, Phyllis R. et al., "Molecular Epidemiology of Adenovirus Type 35 Infections in Immunocompromised Hosts," <i>The Journal of Infectious Diseases</i> , 155:1127-34, 1987 (Exhibit 44)
		Flomenberg, Phyllis et al., "Increasing Incidence of Adenovirus Disease in Bone Marrow Transplant Recipients," <i>The Journal of Infectious Diseases</i> , 169:775-81, 1994 (Exhibit 45)
		Forrester, William C. et al., "A developmentally stable chromatin structure in the human β -globin gene cluster," <i>Proc Natl Acad Sci USA</i> , 83:1359-63, 1986 (Exhibit 46)
		Fraser, Peter and Frank Grosveld, "Locus control regions, chromatin activation and transcription," <i>Current Opinion in Cell Biology</i> , 10:361-5, 1998 (Exhibit 47)

EXAMINER

DATE CONSIDERED

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	Gall, Jason et al., "Adenovirus Type 5 and 7 Capsid Chimera: Fiber Replacement Alters Receptor Tropism without Affecting Primary Immune Neutralization Epitopes," <i>Journal of Virology</i> , 70:2116-23, 1996 (Exhibit 48)
	Gonzales, R. et al., "Increased gene transfer in acute myeloid leukemic cells by an adenovirus vector containing a modified fiber protein," <i>Gene Therapy</i> , 6:314-20, 1999 (Exhibit 49)
	Goodell, Margaret A. et al., "Dye efflux studies suggest that hematopoietic stem cells expressing low or undetectable levels of CD34 antigen exist in multiple species," <i>Nature Medicine</i> , 3:1337-45, 1997 (Exhibit 50)
	Grosveld, Frank et al., "The Dynamics of Globin Gene Expression and Gene Therapy Vectors," <i>Seminars in Hematology</i> , 35:105-111, 1998 (Exhibit 51)
	Gruber, William C. et al., "Fiber Gene and Genomic Origin of Human Adenovirus Type 4," <i>Virology</i> , 196:603-611, 1993 (Exhibit 52)
	Heffelfinger, Sue C. et al., "SK HEP-1: A Human Cell Line of Endothelial Origin," <i>In Vitro Cellular and Developmental Biology</i> , 28A:136-42, 1992 (Exhibit 53)
	Hitt, Mary M. et al., "Human Adenovirus Vectors for Gene Transfer into Mammalian Cells," <i>Advances in Pharmacology</i> , J. Thomas August (ed.), Academic Press, 40:137-206, 1997 (Exhibit 54)
	Horwitz, Marshall S., "Adenoviruses," <i>Fields Virology</i> , 3 rd Edition, B.N. Fields et al. (eds.), Lippincott-Raven Publishers, PA, 2:2149-71, 1996 (Exhibit 55)
	Hsu, Kuo-Hom Lee et al., "A Monoclonal Antibody Specific for the Cellular Receptor for the Group B Coxsackieviruses," <i>Journal of Virology</i> , 62:1647-52, 1988 (Exhibit 56)
	Huang, Shuang et al., "Upregulation of Integrins $\alpha\beta 3$ and $\alpha\beta 5$ on Human Monocytes and T Lymphocytes Facilitates Adenovirus-Mediated Gene Delivery," <i>Journal of Virology</i> , 69:2257-63, 1995 (Exhibit 57)
	Huang, Shuang et al., "Adenovirus Interaction with Distinct Integrins Mediates Separate Events in Cell Entry and Gene Delivery to Hematopoietic Cells," <i>Journal of Virology</i> , 70:4502-8, 1996 (Exhibit 58)
	Ikuta, Koichi and Irving L. Weissman, "Evidence that hematopoietic stem cells express mouse <i>c-kit</i> but do not depend on steel factor for their generation," <i>Proc Natl Acad Sci USA</i> , 89:1502-6, 1992 (Exhibit 59)
	Kay, Mark A. et al., "Therapeutic Serum Concentrations of Human Alpha-1-Antitrypsin After Adenoviral-Mediated Gene Transfer Into Mouse Hepatocytes," <i>Hepatology</i> , 21:815-9, 1995 (Exhibit 60)
	Kirby, Ian et al., "Identification of Contact Residues and Definition of the CAR-Binding Site of Adenovirus Type 5 Fiber Protein," <i>Journal of Virology</i> , 74:2804-3, 2000 (Exhibit 61)
	Klehr, Dagmar et al., "Scaffold-Attached Regions from the Human Interferon β Domain Can Be Used To Enhance the Stable Expression of Genes under the Control of Various Promoters," <i>Biochemistry</i> , 30:1264-70, 1991 (Exhibit 62)
	Koivunen, Erkki et al., "Phage Libraries Displaying Cyclic Peptides with Different Ring Sizes: Ligand Specificities of the RGD-Directed Integrins," <i>Bio/Technology</i> , 13:265-70, 1995 (Exhibit 63)
	Koivunen, Erkki et al., "Tumor targeting with a selective gelatinase inhibitor," <i>Nature Biotechnology</i> , 17:768-74, 1999 (Exhibit 64)

EXAMINER

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Krasnykh, Victor N. et al., "Generation of Recombinant Adenovirus Vectors with Modified Fibers for Altering Viral Tropism," <i>Journal of Virology</i> , 70:6839-46, 1996 (Exhibit 65)
		Krasnykh, Victor et al., "Characterization of an Adenovirus Vector Containing a Heterologous Peptide Epitope in the HI Loop of the Fiber Knob," <i>Journal of Virology</i> , 72:1844-52, 1998 (Exhibit 66)
		Krause, Diane S. et al., "Regulation of CD34 expression in differentiating M1 cells," <i>Experimental Hematology</i> , 25:1051-61, 1997 (Exhibit 67)
		Kwoh, T. Jesse et al., "Introduction and expression of the bacterial <i>PaeR7</i> methylase gene in mammalian cells," <i>Proc Natl Acad Sci USA</i> , 83:7713-7, 1986 (Exhibit 68)
		Langer, Stephen J. and Jerome Schaack, "293 Cell Lines That Inducibly Express High Levels of Adenovirus Type 5 Precursor Terminal Protein," <i>Virology</i> , 221:172-9, 1996 (Exhibit 69)
		Legrand, V. et al., "Fiberless Recombinant Adenoviruses: Virus Maturation and Infectivity in the Absence of Fiber," <i>Journal of Virology</i> , 73:907-19, 1999 (Exhibit 70)
		Li, Qiliang et al., "Development of Viral Vectors for Gene Therapy of β -Chain Hemoglobinopathies: Optimization of a γ -Globin Gene Expression Cassette," <i>Blood</i> , 93:2208-16, 1999 (Exhibit 71)
		Lieber, André et al., "Adenovirus-Mediated Transfer of the Amphotropic Retrovirus Receptor cDNA Increases Retroviral Transduction in Cultured Cells," <i>Human Gene Therapy</i> , 6:5-11, 1995 (Exhibit 72)
		Lieber, André and Mark A. Kay, "Adenovirus-Mediated Expression of Ribozymes in Mice," <i>Journal of Virology</i> , 70:3153-8, 1996 (Exhibit 73)
		Lieber, André et al., "Elimination of Hepatitis C Virus RNA in Infected Human Hepatocytes by Adenovirus-Mediated Expression of Ribozymes," <i>Journal of Virology</i> , 70:8782-91, 1996 (Exhibit 74)
		Lieber, André et al., "Recombinant Adenoviruses with Large Deletions Generated by Cre-Mediated Excision Exhibit Different Biological Properties Compared with First-Generation Vectors In Vitro and In Vivo," <i>Journal of Virology</i> , 70:8944-60, 1996 (Exhibit 75)
		Lieber, André et al., "The Role of Kupffer Cell Activation and Viral Gene Expression in Early Liver Toxicity after Infusion of Recombinant Adenovirus Vectors," <i>Journal of Virology</i> , 71:8798-807, 1997 (Exhibit 76)
		Lieber, André et al., "Inhibition of NF- κ B Activation in Combination with Bcl-2 Expression Allows for Persistence of First-Generation Adenovirus Vectors in the Mouse Liver," <i>Journal of Virology</i> , 72:9267-77, 1998 (Exhibit 77)
		Lieber, André et al., "Integrating Adenovirus - Adeno-Associated Virus Hybrid Vectors Devoid of All Viral Genes," <i>Journal of Virology</i> , 73:9314-24, 1999 (Exhibit 78)
		Lietner, Agnes et al., "Lack of DNA synthesis among CD34 ⁺ cells in cord blood and in cytokine-mobilized blood," <i>British Journal of Haematology</i> , 92:255-62, 1996 (Exhibit 79)
		Lyu, Yi Lisa et al., "Inversion/Dimerization of Plasmids Mediated by Inverted Repeats," <i>Journal of Molecular Biology</i> , 285:1485-501, 1999 (Exhibit 80)
		Maizel, Jacob V., Jr. et al., "The Polypeptides of Adenovirus - Evidence for Multiple Protein Components in the Virion and a Comparison of Types 2, 7A, and 12," <i>Virology</i> , 36:115-25, 1968 (Exhibit 81)

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	November 30, 2001	1633

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Malik, Punam et al., "Recombinant Adeno-Associated Virus Mediates a High Level of Gene Transfer but Less Efficient Integration in the K562 Human Hematopoietic Cell Line," <i>Journal of Virology</i> , 71:1776-83, 1997 (Exhibit 82)
		Martin, David I. K. et al., "Regulation of β -globin gene expression: straightening out the locus," <i>Current Opinion in Genetics & Development</i> , 6:488-95, 1996 (Exhibit 83)
		Mathias, P. et al., "Multiple Adenovirus Serotypes Use α v-Integrins for Infection," <i>Journal of Virology</i> , 68:6811-4, 1994 (Exhibit 84)
		Matsunaga, Takuya et al., "Thrombopoietin Promotes the Survival of Murine Hematopoietic Long-Term Reconstituting Cells: Comparison With the Effects of FLT3/FLK-2 Ligand and Interleukin-6," <i>Blood</i> , 92:452-61, 1998 (Exhibit 85)
		May, Gillian and Tariq Enver, "Targeting gene expression to haemopoietic stem cells: a chromatin-dependent upstream element mediates cell type-specific expression of the stem cell antigen CD34," <i>The EMBO Journal</i> , 14:564-74, 1995 (Exhibit 86)
		McGuckin, Colin P. et al., "A novel approach to investigating the erythroid lineage, using both receptor analysis and haemoglobin detection," <i>British Journal of Haematology</i> , 95:457-60, 1996 (Exhibit 87)
		Michael, S. I. et al., "Addition of a short peptide ligand to the adenovirus fiber protein," <i>Gene Therapy</i> , 2:660-8, 1995 (Exhibit 88)
		Mitani, Kohnoske et al., "Transduction of Human Bone Marrow by Adenoviral Vector," <i>Human Gene Therapy</i> , 5:941-8, 1994 (Exhibit 89)
		Mittereder, Nanette et al., "Evaluation of the Concentration and Bioactivity of Adenovirus Vectors for Gene Therapy," <i>Journal of Virology</i> , 70:7498-509, 1996 (Exhibit 90)
		Miyazawa, Naoki et al., "Fiber Swap between Adenovirus Subgroups B and C Alters Intracellular Trafficking of Adenovirus Gene Transfer Vectors," <i>Journal of Virology</i> , 73:6056-65, 1999 (Exhibit 91)
		Mizuguchi, Hiroyuki and Mark A. Kay, "Efficient Construction of a Recombinant Adenovirus Vector by an Improved <i>In Vitro</i> Ligation Method," <i>Human Gene Therapy</i> , 9:2577-83, 1998 (Exhibit 92)
		Mohler, William A. and Helen M. Blau, "Gene expression and cell fusion analyzed by <i>lacZ</i> complementation in mammalian cells," <i>Proc Natl Acad Sci USA</i> , 93:12423-7, 1996 (Exhibit 93)
		Moore, Kateri A. et al., "In Vitro Maintenance of Highly Purified, Transplantable Hematopoietic Stem Cells," <i>Blood</i> , 89:4337-47, 1997 (Exhibit 94)
		Neering, Sarah J. et al., "Transduction of Primitive Human Hematopoietic Cells With Recombinant Adenovirus Vectors," <i>Blood</i> , 88:1147-55, 1996 (Exhibit 95)
		Nelson, James E. and Mark A. Kay, "Persistence of Recombinant Adenovirus In Vivo Is Not Dependent on Vector DNA Replication," <i>Journal of Virology</i> , 71:8902-7, 1997 (Exhibit 96)
		Neu, Stefan et al., "Isolation and Phenotypic Characterization of CD117-Positive Cells," <i>Leukemia Research</i> , 20:963-71, 1996 (Exhibit 97)
		Nicolás, Andrea L. et al., "Creation and Repair of Specific DNA Double-Strand Breaks <i>in Vivo</i> Following Infection with Adenovirus Vectors Expressing <i>Saccharomyces cerevisiae</i> HO Endonuclease," <i>Virology</i> , 266:211-24, 2000 (Exhibit 98)
		Osawa, Masatake et al., "Long-Term Lymphohematopoietic Reconstitution by a Single CD34-Low/Negative Hematopoietic Stem Cell," <i>Science</i> , 273:242-5, 1996 (Exhibit 99)

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FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number 30429.2USWO	Application Number 09/980,564
	Applicant André Lieber et al.	
	Filing Date November 30, 2001	Group Art Unit 1633

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Papayannopoulou, Thalia et al., "Insights into the cellular mechanisms of erythropoietin-thrombopoietin synergy," <i>Experimental Hematology</i> , 24:660-9, 1996 (Exhibit 100)
		Papayannopoulou, T. and C. Craddock, "Homing and Trafficking of Hemopoietic Progenitor Cells," <i>Acta Haematologica</i> , 97:97-104, 1997 (Exhibit 101)
		Pasqualini, Renata and Erkki Ruoslahti, "Organ targeting <i>in vivo</i> using phage display peptide libraries," <i>Nature</i> , 380:364-6, 1996 (Exhibit 102)
		Pring-Åkerblom, Patricia et al., "Molecular Characterization of Hemagglutination Domains on the Fibers of Subgenus D Adenoviruses," <i>Journal of Virology</i> , 72:2297-304, 1998 (Exhibit 103)
		Qing, Keyun et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Correlation of Tyrosine Phosphorylation of the Cellular Single-Stranded D Sequence-Binding Protein with Transgene Expression in Human Cells In Vitro and Murine Tissues In Vivo," <i>Journal of Virology</i> , 72:1593-9, 1998 (Exhibit 104)
		Recchia, Alessandra et al., "Site-specific integration mediated by a hybrid adenovirus/adeno-associated virus vector," <i>Proc Natl Acad Sci USA</i> , 96:2615-20, 1999 (Exhibit 105)
		Roberts, Andrew W. and Donald Metcalf, "Noncycling State of Peripheral Blood Progenitor Cells Mobilized by Granulocyte Colony-Stimulating Factor and Other Cytokines," <i>Blood</i> , 86:1600-5, 1995 (Exhibit 106)
		Roelvink, Peter W. et al., "Comparative Analysis of Adenovirus Fiber-Cell Interaction: Adenovirus Type 2 (Ad2) and Ad9 Utilize the Same Cellular Fiber Receptor but Use Different Binding Strategies for Attachment," <i>Journal of Virology</i> , 70:7614-21, 1996 (Exhibit 107)
		Roelvink, Peter W. et al., "The Coxsackievirus-Adenovirus Receptor Protein Can Function as a Cellular Attachment Protein for Adenovirus Serotypes from Subgroups A, C, D, E, and F," <i>Journal of Virology</i> , 72:7909-15, 1998 (Exhibit 108)
		Rouet, Philippe et al., "Expression of a site-specific endonuclease stimulates homologous recombination in mammalian cells," <i>Proc Natl Acad Sci USA</i> , 91:6064-8, 1994 (Exhibit 109)
		Roy, Vivek and Catherine M. Verfaillie, "Expression and function of cell adhesion molecules on fetal liver, cord blood and bone marrow hematopoietic progenitors: Implications for anatomical localization and developmental stage specific regulation of hematopoiesis," <i>Experimental Hematology</i> , 27:302-12, 1999 (Exhibit 110)
		Russell, David W. et al., "Adeno-associated virus vectors preferentially transduce cells in S phase," <i>Proc Natl Acad Sci USA</i> , 91:8915-9, 1994 (Exhibit 111)
		Russell, David W. et al., "DNA synthesis and topoisomerase inhibitors increase transduction by adeno-associated virus vectors," <i>Proc Natl Acad Sci USA</i> , 92:5719-23, 1995 (Exhibit 112)
		Rutledge, Elizabeth A. and David W. Russell, "Adeno-Associated Virus Vector Integration Junctions," <i>Journal of Virology</i> , 71:8429-36, 1997 (Exhibit 113)
		Samulski, Richard Jude et al., "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression," <i>Journal of Virology</i> , 63:3822-8, 1989 (Exhibit 114)
		Sánchez, Mariá-José et al., "Characterization of the First Definitive Hematopoietic Stem Cells in the AGM and Liver of the Mouse Embryo," <i>Immunity</i> , 5:513-25, 1996 (Exhibit 115)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Schiedner, Gudrun et al., "Genomic DNA transfer with a high-capacity adenovirus vector results in improved <i>in vivo</i> gene expression and decreased toxicity," <i>Nature Genetics</i> , 18:180-3, 1998 (Exhibit 116)
		Shakibaei, Mehdi and Ute Frevert, "Dual Interaction of the Malaria Circumsporozoite Protein with the Low Density Lipoprotein Receptor-related Protein (LRP) and Heparan Sulfate Proteoglycans," <i>The Journal of Experimental Medicine</i> , 184:1699-711, 1996 (Exhibit 117)
		Shenk, Thomas, "Adenoviridae: The Viruses and Their Replication," <i>Fields Virology</i> , 3 rd Edition, B.N. Fields et al. (eds.), Lippincott-Raven Publishers, PA, 2:2111-48, 1996 (Exhibit 118)
		Shields, Anthony F. et al., "Adenovirus Infections in Patients Undergoing Bone-Marrow Transplantation," <i>The New England Journal of Medicine</i> , 312:529-33, 1985 (Exhibit 119)
		Shtrichman, Ronit and Tamar Kleinberger, "Adenovirus Type 5 E4 Open Reading Frame 4 Protein Induces Apoptosis in Transformed Cells," <i>Journal of Virology</i> , 72:2975-82, 1998 (Exhibit 120)
		Simmons, Paul J. et al., "c-kit is expressed by primitive human hematopoietic cells that give rise to colony-forming cells in stroma-dependent or cytokine-supplemented culture," <i>Experimental Hematology</i> , 22:157-65, 1994 (Exhibit 121)
		Steinwaerder, Dirk S. et al., "Generation of Adenovirus Vectors Devoid of All Viral Genes by Recombination between Inverted Repeats," <i>Journal of Virology</i> , 73:9303-13, 1999 (Exhibit 122)
		Stevenson, Susan C. et al., "Human Adenovirus Serotypes 3 and 5 Bind to Two Different Cellular Receptors via the Fiber Head Domain," <i>Journal of Virology</i> , 69:2850-7, 1995 (Exhibit 123)
		Stevenson, Susan C. et al., "Selective Targeting of Human Cells by a Chimeric Adenovirus Vector Containing a Modified Fiber Protein," <i>Journal of Virology</i> , 71:4782-90, 1997 (Exhibit 124)
		Tiemessen, Caroline T. and Alistair H. Kidd, "The subgroup F adenoviruses," <i>The Journal of General Virology</i> , 76:481-97, 1995 (Exhibit 125)
		Tollefson, Ann E. et al., "The Adenovirus Death Protein (E3-11.6K) Is Required at Very Late Stages of Infection for Efficient Cell Lysis and Release of Adenovirus from Infected Cells," <i>Journal of Virology</i> , 70:2296-306, 1996 (Exhibit 126)
		Tomko, Richard P. et al., "HCAR and MCAR: The human and mouse cellular receptors for subgroup C adenoviruses and group B coxsackieviruses," <i>Proc Natl Acad Sci USA</i> , 94:3352-6, 1997 (Exhibit 127)
		Van der Vliet, P. C., "Adenovirus DNA Replication," <i>Current Topics in Microbiology and Immunology</i> , W. Doerfler and P. Böhm (eds.), Springer, 2:1-30, 1995 (Exhibit 128)
		Watanabe, Tsutomu et al., "Gene Transfer Into Human Bone Marrow Hematopoietic Cells Mediated by Adenovirus Vectors," <i>Blood</i> , 87:5032-9, 1996 (Exhibit 129)
		Wickham, Thomas J. et al., "Integrins $\alpha_v\beta_3$ and $\alpha_v\beta_5$ Promote Adenovirus Internalization but Not Virus Attachment," <i>Cell</i> , 73:309-19, 1993 (Exhibit 130)
		Wickham, T. J. et al., "Targeting of adenovirus penton base to new receptors through replacement of its RGD motif with other receptor-specific peptide motifs," <i>Gene Therapy</i> , 2:750-6, 1995 (Exhibit 131)
		Wickham, Thomas J. et al., "Targeted Adenovirus Gene Transfer to Endothelial and Smooth Muscle Cells by Using Bispecific Antibodies," <i>Journal of Virology</i> , 70:6831-8, 1996 (Exhibit 132)
		Wickham, Thomas J. et al., "Adenovirus targeted to heparan-containing receptors increases its gene delivery efficiency to multiple cell types," <i>Nature Biotechnology</i> , 14:1570-3, 1996 (Exhibit 133)

EXAMINER	DATE CONSIDERED
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